UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,915	08/20/2001	Paul R. Odgren	07917-120001 / UMMc-34 Tr	7747

7590 05/31/2005

J. PETER FASSE
Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804

EXAMINER	
VIVLEMORE, TRACY ANN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/933,915	ODGREN ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S. 070..

DETAILED ACTION

This restriction requirement supersedes the previous action mailed February 17, 2005. This restriction requirement contains further restriction of claims 2-8. All other inventions are as previously set forth.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-5, drawn to a method of treating insufficient cartilage or insufficient skeletal growth using a TRANCE-inhibiting agent that is an antisense to TRANCE RNA, classifiable in class 514, subclass 44.

II. Claims 2-5, drawn to a method of treating insufficient cartilage or insufficient skeletal growth using a TRANCE-inhibiting agent that is an antisense to TRAF-6 RNA, classifiable in class 514, subclass 44.

III. Claim 7, drawn to a method of treating insufficient cartilage or insufficient skeletal growth using a TRANCE-inhibiting agent that is a TRANCE-binding molecule that sequesters TRANCE to form an inactive complex wherein the agent is an antibody, classifiable in class 530, subclass 387.1.

IV. Claim 8, drawn to a method of treating insufficient cartilage or insufficient skeletal growth using a TRANCE-inhibiting agent that is a TRANCE-binding molecule that sequesters TRANCE to form an inactive complex wherein the agent is an isolated RANK receptor, classifiable in class 530, subclass 387.1.

V. Claims 10-14 and 20, drawn to a method of treating excess cartilage or excess skeletal growth using a TRANCE-increasing agent that is a polypeptide comprising a TNF domain of a TRANCE protein, classifiable in class 514, subclass 12.

VI. Claims 15-19 and 20, drawn to a method of treating excess cartilage or excess skeletal growth using a TRANCE-increasing agent that is a TRAF-6 polypeptide, classifiable in class 514, subclass 12.

VII. Claims 22 and 24, drawn to a method of promoting growth of cartilage with a TRANCE-inhibiting agent that is a TRANCE antisense, classifiable in class 514, subclass 44.

VIII. Claims 23 and 24, drawn to a method of promoting growth of cartilage with a TRANCE-inhibiting agent that is a TRAF6 antisense, classifiable in class 514, subclass 44.

IX. Claim 25 in part, drawn to a method of diagnosing a cartilage disorder in a mammal by detecting the level of TRANCE, classifiable in class 435, subclass 6.

X. Claim 25 in part, drawn to a method of diagnosing a cartilage disorder in a mammal by detecting the level of RANK, classifiable in class 435, subclass 6.

XI. Claim 25 in part, drawn to a method of diagnosing a cartilage disorder in a mammal by detecting the level of TRAF-6, classifiable in class 435, subclass 6.

XII. Claims 26-29, drawn to a method of identifying a TRANCE-inhibiting or TRANCE-increasing compounds, classifiable in class 435, subclass 6.

Special note regarding groups VII and VIII

The examiner has noted that claims 22-24 each depend from claim 20. However, each of these claims refers to a TRANCE-inhibiting agent while claim 9, the parent claim of claim 20, refers to use of a TRANCE-increasing agent. In the interests of compact prosecution these claims are being treated as if they are dependent on claim 21, which refers to TRANCE-inhibiting agents. If applicant elects group V or group VI, the response to this restriction requirement must clarify the proper dependence of the elected claims. Note that if these claims are indeed meant to depend from claim 20 the restriction requirement may be subject to revision.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention I is a method of treating a disorder in a mammal using an antisense to TRANCE RNA, invention II is a method of treating a disorder in a mammal using an antisense to TRAF-6 RNA, invention III is a method of treating a disorder in a mammal using an antibody

and invention IV is a method of treating a disorder in a mammal using an isolated RANK receptor.

2. Furthermore, searching any of inventions I-IV together would impose a serious search burden. In the instant case, prior art searches of methods of treating a disorder in a mammal using an antisense to different genes are not coextensive with prior art searches of methods of treating a disorder in a mammal using antibodies or isolated receptors. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of each method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-IV together.

3. Claim 6 link(s) inventions III and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 6. Claim 1 link(s) inventions I-IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be

subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention V is a method of treating a disorder in a mammal using a polypeptide containing a TNF domain of a TRANCE protein while invention VI is a method of treating a disorder in a mammal using a TRAF-6 polypeptide.

5. Furthermore, searching invention V together with invention VI would impose a serious search burden. In the instant case, prior art searches of methods of treating a disorder in a mammal using a polypeptide containing a TNF domain of a TRANCE protein are not coextensive with prior art searches of methods of treating a disorder in a mammal using a different polypeptide like a TRAF-6 polypeptide. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of each method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of inventions V and VI together.

6. Claim 9 link(s) inventions V and VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 9. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

7. Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention VII is a method of increasing cartilage in a mammal using an antisense to TRANCE RNA while invention VIII is a method of increasing cartilage in a mammal using an antisense to TRAF-6 RNA.

8. Furthermore, searching invention VII together with invention VIII would impose a serious search burden. In the instant case, prior art searches of methods of increasing cartilage in a mammal using an antisense to TRANCE are not coextensive with prior art

searches of methods of increasing cartilage in a mammal using an antisense to a different gene like TRAF-6. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of each method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of inventions VII and VIII together.

9. Claim 21 link(s) inventions VII and VIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 21. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

10. Inventions IX-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention IX is a method of diagnosing a cartilage disorder in a mammal using an antisense to TRANCE RNA while invention X is a method of diagnosing a cartilage disorder in a mammal using an antisense to RANK and invention XI is a method of diagnosing a cartilage disorder in a mammal using an antisense to TRAF-6 RNA.

11. Furthermore, searching any of inventions IX-XI together would impose a serious search burden. In the instant case, prior art searches of methods of diagnosing a cartilage disorder in a mammal using an antisense to TRANCE are not coextensive with prior art searches of methods of diagnosing a cartilage disorder in a mammal using an antisense to a different gene like RANK or TRAF-6. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of each method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions IX-XI together.

12. The group of inventions listed as I-IV is unrelated to the group of inventions listed as V and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions I-IV is to treat a disorder

that is insufficient cartilage or insufficient skeletal growth while the function of inventions V-VI is to treat a disorder that is excess cartilage or excess skeletal growth.

13. Furthermore, searching either of inventions I-IV together with either of inventions V-VI would impose a serious search burden. In the instant case, prior art searches of methods of treating a disorder that is insufficient cartilage or insufficient skeletal growth in a mammal are not coextensive with prior art searches of methods of treating a disorder that is excess cartilage or excess skeletal growth in a mammal. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of each method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-IV and V-VI together.

14. The group of inventions listed as I-IV is unrelated to the group of inventions listed as VII and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions I-IV is to treat a disorder that is insufficient cartilage or insufficient skeletal growth while the function of inventions VII-VIII is to promote growth of cartilage. Each of these groups of inventions has distinct method steps and different target populations. Inventions I-IV are meant to

be performed specifically on subjects having a disorder while inventions VII-VIII could be performed on any subject.

15. Furthermore, searching either of inventions I-IV together with either of inventions VII-VIII would impose a serious search burden. In the instant case, prior art searches of methods of treating a disorder that is insufficient cartilage or insufficient skeletal growth in a mammal are not coextensive with prior art searches of methods of promoting cartilage growth. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of each method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-IV and VII-VIII together.

16. The group of inventions listed as I-IV is unrelated to the group of inventions listed as IX-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions I-IV is to treat a disorder that is insufficient cartilage or insufficient skeletal growth using an antisense while the function of inventions IX-XI is to diagnose a cartilage disorder by assaying protein levels.

17. Furthermore, searching either of inventions I-IV together with any of inventions IX-XI would impose a serious search burden. In the instant case, prior art searches of

methods of treating a disorder that is insufficient cartilage or insufficient skeletal growth in a mammal are not coextensive with prior art searches of methods of diagnosing a cartilage disorder. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of each method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-IV and IX-XI together.

18. The group of inventions listed as I-IV is unrelated to invention XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions I-IV is to treat a disorder that is insufficient cartilage or insufficient skeletal growth using an antisense while the function of invention XII is to identify compounds that can inhibit or increase TRANCE by detecting chondrocyte proliferation.

19. Furthermore, searching either of inventions I-IV together with invention XII would impose a serious search burden. In the instant case, prior art searches of methods of treating a disorder that is insufficient cartilage or insufficient skeletal growth in a mammal are not coextensive with prior art searches of methods of identifying compounds that increase or inhibit TRANCE. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of

each method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-IV and XII together.

20. The group of inventions listed as V and VI are unrelated to the group of inventions listed as VII and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions V-VI is to treat a disorder that is excess cartilage or excess skeletal growth while the function of inventions VII-VIII is to promote growth of cartilage.

21. Furthermore, searching either of inventions V-VI together with either of inventions VII-VIII would impose a serious search burden. In the instant case, prior art searches of methods of treating a disorder that is excess cartilage or excess skeletal growth in a mammal are not coextensive with prior art searches of methods of promoting cartilage growth. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of each method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions V-VI and VII-VIII together.

22. The group of inventions listed as V and VI are unrelated to the group of inventions listed as IX-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions V-VI is to treat a disorder that is excess cartilage or excess skeletal growth using an antisense while the function of inventions IX-XI is to diagnose a cartilage disorder by assaying protein levels.

23. Furthermore, searching either of inventions V-VI together with any of inventions IX-XI would impose a serious search burden. In the instant case, prior art searches of methods of treating a disorder that is excess cartilage or excess skeletal growth in a mammal are not coextensive with prior art searches of methods of diagnosing a cartilage disorder. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of each method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions V-VI and IX-XI together.

24. The group of inventions listed as V and VI are unrelated to invention XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions

have different functions. The function of inventions V-VI is to treat a disorder that is excess cartilage or excess skeletal growth using an antisense while the function of invention XII is to identify compounds that can inhibit or increase TRANCE by detecting chondrocyte proliferation.

25. Furthermore, searching either of inventions V-VI together with invention XII would impose a serious search burden. In the instant case, prior art searches of methods of treating a disorder that is excess cartilage or excess skeletal growth in a mammal are not coextensive with prior art searches of methods of identifying compounds that increase or inhibit TRANCE. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of each method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions V-VI and XII together.

26. The group of inventions listed as VII and VIII are unrelated to the group of inventions listed as IX-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions VII-VIII is to promote growth of cartilage while the function of inventions IX-XI is to diagnose a cartilage disorder by assaying protein levels.

27. Furthermore, searching either of inventions VII-VIII together with any of inventions IX-XI would impose a serious search burden. In the instant case, prior art searches of methods to promote growth of cartilage are not coextensive with prior art searches of methods of diagnosing a cartilage disorder. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of each method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions VII-VIII and IX-XI together.

28. The group of inventions listed as VII and VIII are unrelated to invention XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions VII-VIII is to promote growth of cartilage while the function of invention XII is to identify compounds that can inhibit or increase TRANCE by detecting chondrocyte proliferation.

29. Furthermore, searching either of inventions VII-VIII together with invention XII would impose a serious search burden. In the instant case, prior art searches of methods to promote growth of cartilage are not coextensive with prior art searches of methods of identifying compounds that increase or inhibit TRANCE. Search of each of these inventions would require different key word searches of each compound and of

each distinctive step of each method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions VII-VIII and XII together.

30. The group of inventions listed as IX-XI is unrelated to invention XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions IX-XI is to diagnose a cartilage disorder while the function of invention XII is to identify compounds that can inhibit or increase TRANCE by detecting chondrocyte proliferation.

31. Furthermore, searching either of inventions IX-XI together with invention XII would impose a serious search burden. In the instant case, prior art searches of methods to diagnose a cartilage disorder are not coextensive with prior art searches of methods of identifying compounds that increase or inhibit TRANCE. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of each method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions IX-XI and XII together.

Restriction to a single nucleotide or amino acid sequence

32. Claims 3, 12 and 13 are subject to an additional restriction since they are not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1)share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

33. Claim 3 specifically claims TRANCE antisense SEQ ID NOS 17 and 18, which are targeted to and modulate the expression of TRANCE. Although the antisense sequences claimed each target and modulate expression of TRANCE, the instant antisense sequences are considered to be unrelated, since each antisense sequence claimed is structurally and functionally independent and distinct for the following

reasons: each antisense sequence has a unique nucleotide sequence and each antisense sequence targets a different and specific region of a TRANCE nucleic acid. As such the Markush/genus of antisense sequences in claim 3 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the antisense sequences claimed in claim 3 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search in terms of computer time needed to perform the search and the subsequent analysis of the search results by the examiner. In view of the foregoing, one (1) antisense sequence is considered to be a reasonable number of sequences for examination. Accordingly, if group I is elected applicants are required to elect one (1) antisense sequence from claim 3. Note that this is not a species election.

34. Claims 12 and 13 specifically claim TRANCE-increasing polypeptide SEQ ID NOS 3-8, which are targeted to TRANCE. Although the polypeptide sequences claimed each target TRANCE, the instant sequences are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each sequence has a unique amino acid sequence and each sequence targets a different and specific region of TRANCE. As such the Markush/genus of sequences in claims 12 and 13 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the sequences claimed in claims 12 and 13 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search in terms of computer time needed to perform the search and the subsequent analysis of the search

results by the examiner. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, if group V is elected applicants are required to elect one (1) sequence from claims 12 and 13. Note that this is not a species election.

35. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

36. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
May 22, 2005

JAMES SCHULTZ
PATENT EXAMINER